

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

26/JUN/2012

**MEMORANDUM** 

Subject:

Name of Pesticide Product: TC-335

EPA Reg. No. /File Symbol: 499-LAG

DP Barcode:

D400661

Decision No: Action Code:

459858 R310

PC Code:

129121 (fipronil)

It & M. Clinder of Hashing T.C. Tox 1000007

From:

Eugenia McAndrew, Biologist

Technical Review Branch

Registration Division (7505P)

To:

Clayton Myers, RM Team 10

Insecticide Branch

Registration Division (7505P)

Applicant:

Whitmire Micro-Gen Research Laboratories, Inc.

3568 Tree Court Ind. Blvd.

St. Louis, MO 63122

FORMULATION FROM LABEL:

Active Ingredient(s):

<u>% by wt.</u> ⋅

**Fipronil** 

0.005

Other Ingredients:

99.995

Total:

100.000%

**ACTION REQUESTED:** The Risk Manager requests: "Registrant has applied for a new fipronil product with a formulation and uses already registered (aerosol foam). They want to bridge tox data from a previously registered product, per the transmittal documentation, for which the fipronil concentration is more than 10x higher (0.06% vs. 0.005%), and they are citing the studies associated with that product."

**BACKGROUND**: Whitmire Micro-Gen Research Laboratories, Inc. has applied for registration of TC-335, EPA File Symbol 499-LAG. To satisfy the acute toxicity data requirements, the registrant is citing data used to support the registration of TC-300, EPA Reg. No. 499-545. Both products are ready-to-use formulations in pressurized containers containing fipronil as the active ingredient (0.06% in the cited product vs. 0.005% in the proposed product). The submission includes a basic CSF and alternate #1 CSF both dated January 25, 2012, a label, data matrix and company letter.

The data matrix cites acute toxicity studies with MRIDs 479121-02 to -07. A search of the OPP electronic databases shows that these studies were submitted to support the registration of TC-300, EPA Reg. No. 499-545. They were reviewed and classified s acceptable in a prior TRB memo (McAndrew; D380713; EPA File Symbol 499-LUL; 12/APR/2011).

## RECOMMENDATIONS:

- 1. TRB compared the basic CSFs of the proposed product, 499-LAG, and the cited product, 499-545, and determined that the formulations are toxicologically similar. The cited acute toxicity data referenced above may be used to support the registration of the proposed product.
- 2. The acute toxicity profile for the proposed product, TC-335, EPA File Symbol 499-LAG, is as follows:

acute oral toxicity	IV	cited	MRID 47912102
acute dermal toxicity	IV	cited	MRID 47912103
acute inhalation toxicity	IV	cited	MRID 47912107
primary eye irritation	IV ·	cited	MRID 47912104
primary skin irritation	IV	cited	MRID 47912105
dermal sensitization	negative	cited	MRID 47912106

3. The proposed basic and alternate CSFs submitted for 499-LAG must be reviewed and accepted by the TRB Product Chemistry Team.

**LABELING**: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #:

000499-00563

PRODUCT NAME:

TC-335

**PRECAUTIONARY STATEMENTS** 

**SIGNAL WORD:** 

CAUTION

(optional)

## **Hazards to Humans and Domestic Animals:**

First Aid: No statements are required. Category III statements may be used.